DIA Workshop
GUIDANCE FOR INDUSTRY: Regulatory Submissions in Electronic Format

David Isom
Acting Director, Office of Information Technology
Center for Drug Evaluation and Research
September 25, 1997

Session I: Introduction

- CDER IT Focus
  - Capability for electronic regulatory submission and review by 2002
- Areas of concentration
  - Focused IT supporting cast and planning
  - **e-collection, submission, and archive (Today's topic: submission and archive)**
  - e-review and resources
  - e-document management system
  - e- access for the public (web)

Electronic Submission

- You can submit regulatory submissions in electronic format in lieu of paper provided:
  - regulations (21 CFR part 11) are met, and
  - document type is identified in the Agency's public docket (no. 92S-251)
- Guidance for CDER's first document types
  - CRF/CRTs subsections of the New Drug Application (NDA)
  - This will replace CDER's waiver policy

Background: CRT/CRF subsections

- CRT/CRF and Archiving Groups formed
- Draft Guidances introduced at a Nov 96 DIA
- Based on internal and external comments, we combined the Guidances to one
- Further stds and function work continues
- Today's CDER speakers are key contributors to this new guidance

Session II: Organization of the Guidance

- Introduction
- Organization of the guidance
- File formats for archiving
- Other file formats
- Organization and submission
- Specific submission (document) types
  - follows the 356h form

Introduction

- Voluntary to submit the document types we publish in the public docket
- Reduces the need to consult CDER on details that ensure your e-submissions can be handled, reviewed, and maintained
- The ‘Archiving Submissions in Electronic Format--NDAs’ is a first of a series.

File Formats for Archiving

- What CDER is prepared to archive and accept in lieu of paper regulatory copy
- PDF (portable document format)
- General information
  - reasons for selection
  - recommendations for fonts, page orientation, indexing, hypertext linking, etc.

Other File Formats (OFF)

- Any electronic format or functionality not covered in the archive guidance:
  - Needed because we can't do everything at once
  - Submit directly to the review division as you do in today's 'CANDA' model. However,
  - will not be acceptable to replace the paper
- The archive guidance will increase as we gain experience and as technology improves so we can decrease OFF submissions
- Our years of CANDAs and OFFs got us here

Submitting Archival Files

- Organization of the files and directories
- Where to submit the single copy
- Media we can manage
- How to label and bind the media
- Include a paper copy of the cover letter, 356h, and table of contents

Amendments

- Amendments to the specified document types will follow as soon as possible. However, the first priority is to complete all subsections of the initial application.

Subsections- follows the 356h form

- Contents
  - Each subsection provides regulatory references and recommendations for file organization, information fields, TOC, hypertext linking, and indexing recommendations
- Only item 1 (Index), item 11 (CRTs) and item 12 (CRFs) will be in the guidance to start
  - Only item 11 and 12 are initially in the docket
- Several other subsections are already in draft
- Data? Coming, but have more work to do

Technical Support and Questions

- Mr. Ken Edmunds, OIT Electronic Submissions Coordinator, email ESUB@CDER.fda.gov